**MYTECH TECHNOLOGY CO., LTD.**
5F.6, Alley 2, Lane 222, Lien Cheng Road,
Chung Ho City, Taipei Hsien, 235, Taiwan, ROC
Telephone: 886-2-2247 4816 Fax: 886-2-2247 7024
Email: sale@mytech.com.tw

MAY 17 2004

# "510(k) Summary"

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|---|---|
| Submitter's Name: | *MYTECH TECHNOLOGY CO., LTD.* |
| Address: | *5F.6, Alley 2, Lane 222, Lien Cheng Road, Chung Ho City, Taipei Hsien, 235, Taiwan, ROC* |
| Telephone: | 886-2-2247 4816 |
| FAX: | 886-2-2247 7024 |
| Contact Person: | Dr. Jen, Ke-Min |
| Date Summary Prepared: | 5/7/2004 |
| Proprietary Name: | MYTECH WRIST BLOOD PRESSURE MONITOR, HPL-200 |
| Common Name: | BLOOD PRESSURE MONITOR |
| Classification Name: | NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM<br>( per 21CFR section 870.1130) |
| Device Class: | Class II (performance standards) |
| Specialty: | CARDIOVASCULAR |
| Product code: | DXN |
| Legally Marketed ( Predicate ) Device : | MYTECH WRIST BLOOD PRESSURE MONITOR, HPL-100<br>510(k) No: **K030561** |

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## Description of the new device:

Basically, the subject device and the predicated device are the same in intended use, technological characteristics, power supply, LCD display, range, accuracy, and operating environments, memory, dimensions, weight, and storage environments. The only difference is the display layout. We present two photos for HPL-100 and HPL-200 respectively in the following page for comparison. Since we also did the relevant electric safety and EMC testing for HPL-200, the safety and effectiveness aspects are not raised.

**They are decided to be substantially equivalent.**

## Technological Characteristics of our new device compared to the predicate device:

The technological characteristic of MYTECH HPL-100 is substantially equivalent to HPL-200. MYTECH HPL-100 is of generally the same form and intended to be used in the same manner as the substantially equivalent product; and is passed the relevant EMC and Safety standards. Thus there are substantially equivalent.

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## Test Summary:

1. **ELECTRIC SAFETY and EMC test reports,**

| | | |
|---|---|---|
| *General safety* | *EN 60601-1:1990+A1+A2+A11+A12+A13* | ***PASS*** |
| *EMC conformity* | *EN 60601-1-2: 1993* | ***PASS*** |

2. **WOVEN COTTON SHEETING**

   Uses the 510K Blood-Pressure Cuff

3. **PERFORMANCE & CLINICAL TEST**
   AAMI / ANSI SP10

***MYTECH TECHNOLOGY CO., LTD.*** *believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.*

JAMES WU

Submitter, 5/7/2004
*General Manager*
***MYTECH TECHNOLOGY CO., LTD.***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Mytech Technology Co., Ltd.
c/o Dr. Ke-Min Jen
Roc Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K041228
Trade Name: Mytech/Happy Life Blood Pressure Monitor, HPL-200
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 07, 2004
Received: May 10, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041228

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510(k) Number ( if known): K041228

Device Name: *MYTECH / HAPPY LIFE BLOOD PRESSURE MONITOR, HPL-200*

*Indications for use:*

The device is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.25" – 7.75".

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K041228



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